## IN THE CLAIMS:

The text of all pending claims, (including withdrawn claims) is set forth below. Cancelled and not entered claims are indicated with claim number and status only. The claims as listed below show added text with <u>underlining</u> and deleted text with <u>strikethrough</u>. The status of each claim is indicated with one of (original), (currently amended), (cancelled), (withdrawn), (new), (previously presented), or (not entered).

Please AMEND claims 1-12 and 15-20, and ADD new claims 21-23 in accordance with the following:

1. (Currently amended) An acetone-free process for the preparation of Gabapentin of the following formula 4

which consists essentially of:

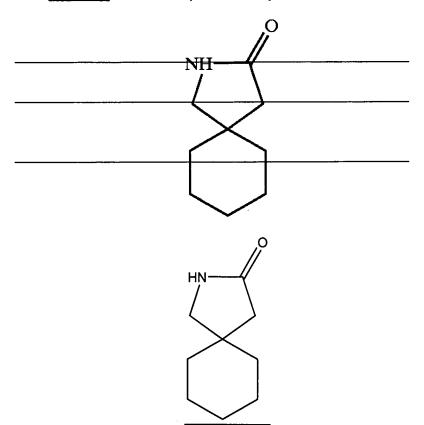
- (i) preparing an ethanol-free aqueous solution of Gabapentin hydrochloride in water in a ratio of one part by weight of the Gabapentin hydrochloride to 0.5 to 3 parts by weight of the water;
- (ii) preparing an aqueous solution of an alkali metal base in a concentration in the range of 40-50% w/w;
- (iii) adding 0.08 to 0.3 parts by weight of the solution obtained in step
  (ii) to 1.5 to 4 parts by weight of the solution obtained in step (i) at
  a temperature in the range of 0 to 20 degree C to form a resulting
  solution;
- (iv) heating the resulting solution gradually to a temperature in the range of 60-90 degree C;

- (v) gradually cooling the resulting solution to a temperature in the range of 0 to 15 degree C to obtain a precipitate;
- (vi) aging the precipitate for a period of time in the range of 0.5 hrs to 8 hrs at a temperature in the range of 0 to 15 degree C;
- (vii) separating the precipitate from its mother liquor by conventional methods; and
- (viii) recrystallising-recrystallizing the precipitate from a mixture of isopropyl alcohol-(IPA), methanol &-and water in a ratio ranging from 4.54-19.64: 3.88-15.64: 1 (v/v), wherein the ratio of isopropyl alcohol to methanol is in the range from 0.58: 1 to 1.32: 1 (v/v), to get Gabapentin of over 99.5% purity and another mother liquor,

wherein the Gabapentin has a chloride content of 100 ppm or less.

- 2. (Currently Amended) The process as claimed in claim 1, wherein the amount of the gabapentin-Gabapentin hydrochloride and the water used-in step (i) is in the ratio of 0.5 to 2.5 parts of water to 1 part of the Gabapentin hydrochloride or in the ratio of 1.5 to 2.5 parts of the water to 1 part of the Gabapentin hydrochloride.
- (Currently Amended) The process as claimed in claim 1, wherein the alkali metal base used in step (ii) is sodium hydroxide, or potassium hydroxide.
- 4. (Currently Amended) The process as claimed in claim 1, wherein the solution of the alkali metal base used in step (ii) is in a concentration in the range of 40-50% w/w in water or in the concentration in the range of 45-50% w/w in water.
- (Currently Amended) The process as claimed in claim 1, wherein the temperature employed in step (iii) is 10 to 20 deg C, or 10 to 15 deg C.
- 6. (Currently Amended) The process as claimed in claim 1, wherein the temperature employed in step (iv) used is in the range of 60 to 75 deg C or in the range of 60 to 70 deg C.

- 7. (Currently Amended) The process as claimed in claim 1, wherein the temperature employed in step (v) is in the range of 5 to 15 degree C-or in the range of 5 to 10 degree C.
- 8. (Currently Amended) The process as claimed in claim 1, wherein the time employed-for aging the precipitate in step (vi) is between 0.5 to 3 hrs-or between 0.5 to 1 hr.
- 9. (Currently Amended) The process as claimed in claim 1, wherein the separation of Gabapentin-the precipitate in step (vii) is effected by filtration or centrifugation.
- **10.** (Currently amended) An acetone-free process for the preparation of Gabalactam of the following formula-3-represented by:



(i) preparing an <u>ethanol-free</u> aqueous solution of Gabapentin hydrochloride in water in a ratio of one part by weight of the

- Gabapentin hydrochloride to 0.5 to 3 parts by weight of the water:
- (ii) preparing an aqueous solution of an alkali metal base in a concentration in the range of 40-50% w/w;
- (iii) adding 0.08 to 0.3 parts by weight of the solution obtained in step (ii) to 1.5 to 4 parts by weight of the solution obtained in step (i) at a temperature in the range of 0 to 20 degree C to form a resulting solution;
- (iv) heating the resulting solution gradually to a temperature in the range of 60-90 degree C;
- (v) gradually cooling the resulting solution to a temperature in the range of 0 to 15 degree C to obtain a precipitate;
- (vi) aging the precipitate for a period of time in the range of 0.5 hrs to 8 hrs at a temperature in the range of 0 to 15 degree C;
- (vii) separating the precipitate from its mother liquor-by conventional methods;
- (viii) recrystallising recrystallizing the precipitate from a mixture of isopropyl alcohol (IPA), methanol & and water in a ratio ranging from 4.54-19.64: 3.88-15.64: 1 (v/v), wherein the ratio of isopropyl alcohol to methanol is in the range from 0.58:1 to 1.32:1 (v/v), to get Gabapentin of over 99.5% purity, wherein the Gabapentin has a chloride content of 100 ppm or less, and another mother liquor;
- (ix) treating the mother liquors from steps (vii) & (viii) with <u>an</u> aqueous <u>solution of</u> sodium hydroxide in a concentration in the range of 5 to 20% at a temperature in the range of 80 to 100 degree C; and
- (x) recovering the Gabalactam from step (ix) by extraction with organic solvents.
- 11. (Currently Amended) The process as claimed in claim 10, wherein in step (ix), the concentration of the solution of sodium hydroxide ranges from 10 to 20%, and the temperature ranges from 80 to 85 degree C.

- **12.** (Currently Amended) The process as claimed in claim 10, wherein in step (x), the recovery of Gabalactam is effected by extraction with organic solvents are selected from the group consisting of toluene, ethylene dichloride, methylene dichloride and hexane.
- 13. (Canceled)
- **14.** (Previously presented) The process as claimed in claim 1, wherein the chloride content is 40 to 95 ppm.
- **15.** (Currently Amended) The process as claimed in claim 441, wherein the chloride content is 40 to 90 ppm.
- **16.** (Currently Amended) The process as claimed in claim 451, wherein the chloride content is 40 to 70 ppm.
- **17.** (Currently Amended) The process as claimed in claim 461, wherein the chloride content is 40 to 60 ppm.
- **18.** (Currently Amended) The process as claimed in claim <u>471</u>, wherein the chloride content is 40 to 50 ppm.
- **19.** (Currently amended) An acetone-free process for the preparation of Gabapentin of the following formula 4

- (i) providing an ethanol-free aqueous solution of Gabapentin hydrochloride having a ratio of parts by weight of Gabapentin hydrochloride to parts by weight of water from 0.5 to 3;
- (ii) at a temperature in the range from 0 to 20 degree C, adding 0.08 to 0.3 parts by weight of an aqueous alkali metal base solution at a concentration from 40 to 50% w/w to 1.5 to 4 parts by weight of the aqueous solution of the Gabapentin hydrochloride to form a resulting solution at a temperature in the range from 0 to 20 degree C;
- (iii) heating the resulting solution gradually to a temperature from 60 to 90 degree C;
- (iv) then, gradually cooling the resulting solution gradually to a temperature from 0 to 15 degree C to obtain a precipitate;
- (v) maintaining aging the precipitate in the solution at the temperature from 0 to 15 degree C for a time from 0.5 hrs to 8 hrs;
- (vi) separating the precipitate from its mother liquor; and
- (vii) recrystallising recrystallizing the precipitate from a solvent mixture containing isopropyl alcohol-(IPA), methanol & and water in a ratio ranging from 4.54-19.64: 3.88-15.64: 1 (v/v), wherein the ratio of isopropyl alcohol to methanol is in the range from 0.58: 1 to 1.32: 1 (v/v), to obtain Gabapentin of at least 99.5% purity and having a chloride content of 100 ppm or less, and a Gabalactam content of 0.05% or less,

wherein the process excludes an ion exchange conversion of Gabapentin hydrochloride, and wherein the Gabapentin has a chloride content of 100 ppm or less.

- 20. (Currently Amended) The process of claim 19, wherein the chloride content is from 40 to 50 ppm and the <u>Gaba</u>lactam content is from 0.01 to 0.045%.
- 21. (New) An acetone-free process for the preparation of Gabapentin of the following formula

- (i) preparing an ethanol-free aqueous solution of Gabapentin hydrochloride in water in a ratio of one part by weight of the Gabapentin hydrochloride to 0.5 to 3 parts by weight of the water;
- (ii) preparing an aqueous solution of an alkali metal base in a concentration in the range of 40-50% w/w;
- (iii) adding 0.08 to 0.3 parts by weight of the solution obtained in step
   (ii) to 1.5 to 4 parts by weight of the solution obtained in step (i) at a temperature in the range of 0 to 20 degree C to form a resulting solution;
- (iv) heating the resulting solution gradually to a temperature in the range of 60-90 degree C;
- (v) gradually cooling the resulting solution to a temperature in the range of 0 to 15 degree C to obtain a precipitate;
- (vi) aging the precipitate for a period of time in the range of 0.5 hrs to 8hrs at a temperature in the range of 0 to 15 degree C;
- (vii) separating the precipitate from its mother liquor; and
- (viii) recrystallizing the precipitate from a mixture of isopropyl alcohol, methanol and water in a ratio ranging from 4.54-19.64 : 3.88-15.64 : 1 (v/v), wherein the ratio of isopropyl alcohol to methanol is in the range from 0.58 : 1 to 1.32 : 1 (v/v), to obtain Gabapentin of over 99.5% purity and another mother liquor, wherein the Gabapentin has a chloride content of 100 ppm or less and

wherein the process produces a yield of Gabapentin that is over 50%.

**22.** (New) An acetone-free process for the preparation of Gabalactam of the following formula:

which consists essentially of:

- (i) preparing an ethanol-free aqueous solution of Gabapentin hydrochloride in water in a ratio of one part by weight of the Gabapentin hydrochloride to 0.5 to 3 parts by weight of the water;
- (ii) preparing an aqueous solution of an alkali metal base in a concentration in the range of 40-50% w/w;
- (iii) adding 0.08 to 0.3 parts by weight of the solution obtained in step
   (ii) to 1.5 to 4 parts by weight of the solution obtained in step (i) at a temperature in the range of 0 to 20 degree C to form a resulting solution;
- (iv) heating the resulting solution gradually to a temperature in the range of 60-90 degree C;
- (v) gradually cooling the resulting solution to a temperature in the range of 0 to 15 degree C to obtain a precipitate;
- (vi) aging the precipitate for a period of time in the range of 0.5 hrs to 8 hrs at a temperature in the range of 0 to 15 degree C;
- (vii) separating the precipitate from its mother liquor;
- (viii) recrystallizing the precipitate from a mixture of isopropyl alcohol, methanol and water in a ratio ranging from 4.54-19.64 : 3.88-15.64 : 1 (v/v), wherein the ratio of isopropyl alcohol to methanol is in the range from 0.58 : 1 to 1.32 : 1 (v/v), to obtain Gabapentin of over 99.5% purity, wherein the Gabapentin is produced in a yield of over 50% and has a chloride content of 100 ppm or less, and another mother liquor;

- (ix) treating the mother liquors from steps (vii) & (viii) with an aqueous solution of sodium hydroxide in a concentration in the range of 5 to 20% at a temperature in the range of 80 to 100 degree C; and
- (x) recovering Gabalactam from step (ix) by extraction with organic solvents.
- 23. (New) An acetone-free process for the preparation of Gabapentin of the following formula:

- (i) providing an ethanol-free aqueous solution of Gabapentin hydrochloride having a ratio of parts by weight of Gabapentin hydrochloride to parts by weight of water from 0.5 to 3;
- (ii) adding 0.08 to 0.3 parts by weight of an aqueous alkali metal base solution at a concentration from 40 to 50% w/w to 1.5 to 4 parts by weight of the aqueous solution of the Gabapentin hydrochloride to form a resulting solution at a temperature in the range from 0 to 20 degree C;
- (iii) heating the resulting solution gradually to a temperature from 60 to 90 degree C;
- (iv) gradually cooling the resulting solution to a temperature from 0 to 15 degree C to obtain a precipitate;
- (v) maintaining the precipitate in the solution at the temperature from0 to 15 degree C for a time from 0.5 hrs to 8 hrs;
- (vii) separating the precipitate from its mother liquor; and

(viii) recrystallizing the precipitate from a solvent mixture containing isopropyl alcohol, methanol and water in a ratio ranging from 4.54-19.64: 3.88-15.64: 1 (v/v), wherein the ratio of isopropyl alcohol to methanol is in the range from 0.58: 1 to 1.32: 1 (v/v), to obtain Gabapentin of at least 99.5% purity and having a chloride content of 100 ppm or less, and a Gabalactam content of 0.05% or less, wherein the process excludes an ion exchange conversion of Gabapentin hydrochloride, and wherein the Gabapentin has a chloride content of 100 ppm or

less, and further wherein the process produces Gabapentin in a yield of over